DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-06

DATE: **November 14, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: The Use of Foreign Acquired Drugs in Long-Term Care Facilities

Letter Summary

When a long-term care facility is found acquiring and dispensing foreign drugs to residents, the surveyor must assess whether the facility is compliant with 42 C.F.R. § 483.60(a) which states: "a facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident."

The purpose of this memorandum is to instruct surveyors on what to do when long-term care (LTC) facilities are acquiring and dispensing of foreign drugs for the purpose of consumption by residents.

The regulations at 42 C.F.R. Part 483 subpart B require LTC facilities to ensure the accurate acquiring, receiving, dispensing and administering of all drugs and biologicals. See section 484.60(a) of the State Operations Manual for further information on the factors that the state survey agency and the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) should consider when determining compliance with this regulation.

Background

The United States (U.S.) Department of Health and Human Services (HHS) is very concerned about the safety risks associated with the unauthorized importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U. S. approved prescription drugs have been of unknown quality. These drugs may be sub-potent, super-potent, expired, contaminated, or ineffective. Since they have been manufactured and/or held outside of our regulatory system, HHS cannot provide adequate assurance to the American public that the drug products delivered to consumers in the U. S. from foreign countries are safe and effective for their intended uses. These concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the U. S.

Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective.

Importing prescription drugs into the U. S. may violate the FFDCA in one of two ways. First, many drugs imported into the U. S. from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the U. S. that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

The United States Food and Drug Administration (FDA) approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 C.F.R. § 314.50). Generally, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved (21 U.S.C. § 355). The foreign version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the U.S. a prescription drug that was originally manufactured in the U. S. and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id*. Importing a drug into the U. S. in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any LTC facility that imports prescription drugs into the U.S. must ensure, among other things, that it imports only FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance (21 C.F.R. § 314.50). The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Determining Compliance

When a facility is found acquiring and dispensing, or allowing the dispensing of foreign drugs/medication to residents in LTC facilities, the surveyors must assess whether the facility is compliant with 42 C.F.R. 483.60(a) which states: “a facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.”

We acknowledge that identifying the legal status of drugs dispensed in an LTC facility can be complicated. Indeed, many legal, FDA-approved prescription drugs are manufactured abroad and legally imported into the U. S. for distribution to pharmacies, health care facilities, and other retail outlets. It therefore would be incorrect to conclude that every prescription drug imported into the U. S. from abroad is imported in violation of the FFDCA. Please note, however, that legal FDA-approved prescription drugs imported into the U. S. are generally so imported by the company that manufactured them or by licensed wholesale distributors who work closely with those companies.

If a surveyor becomes aware that an LTC facility is *directly* importing its drugs from foreign countries, that may be a signal that the LTC facility is acquiring those drugs in violation of the FFDCA. If the facility is aware of imported drugs that are not FDA-approved the surveyor should cite the facility for unsafe practice under §483.60(a) pharmacy services and report the finding to the FDA.

When a surveyor finds that an individual residing in a nursing home has in his/her possession imported prescription drugs that are not FDA-approved, the surveyor should ascertain whether the facility is aware of the illegal drug:

- If the facility states that they are unaware of the imported drugs the surveyor should then ascertain whether the drugs are delivered to the resident via the facility staff or are self-administered.

    - If the drugs are administered by facility staff, the surveyor should cite the facility for the unsafe practice under §483.60(a) pharmacy services and report the finding to the FDA.

    - If the resident it self-administering the drugs without the facility's knowledge the surveyor should notify the facility of the unsafe practice.

In addition, virtually all of the prescription drugs imported into the U.S. by individual consumers violate the FFDCA because they are dispensed by foreign pharmacies that stock foreign versions of FDA-approved drugs that lack FDA-approval and/or proper labeling, or because they were originally manufactured in the U.S., sent abroad, and then imported by a person other than the manufacturer in violation of 21 U.S.C. § 381(d)(1). Accordingly, evidence of personal importation is almost certainly an indication that the imported prescription drugs have been obtained in violation of federal law.

In the event that a violative activity is identified, we recommend that, in addition to assessing compliance with 42 C.F.R. 483.60(a), you report the findings to the FDA, which is the agency within HHS that is responsible for enforcing the FFDCA.

The FDA point of contact is:

Ada Irizarry
CDER Office of Compliance
Division of New Drugs and Labeling Compliance
11919 Rockville Pike, Room 348
Rockville, MD 20852
(301) 827-8967 or www.fda.gov

For questions on this memorandum, please contact Debra Swinton-Spears at (410)-786-7506 or e-mail at debra.swinton-spears@cms.hhs.gov.

Effective Date: Immediately. Please ensure that all appropriate staff are fully informed within 30 days of the date of this memorandum, and disseminate the information to affected providers.

Training: The information contained in this announcement should be shared with all nursing home surveyors and supervisors.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)